



UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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TAKEDA CHEMICAL INDUSTRIES, LTD. and
TAKEDA PHARMACEUTICALS NORTH AMERICA,
INC.,

Plaintiffs,

-v-

MYLAN LABORATORIES, INC., MYLAN
PHARMACEUTICALS, INC., and UDL
LABORATORIES, INC.,

Defendants.

TAKEDA CHEMICAL INDUSTRIES, LTD. and
TAKEDA PHARMACEUTICALS NORTH AMERICA,
INC.,

Plaintiffs,

-v-

RANBAXY LABORATORIES, LTD., and RANBAXY
PHARMACEUTICALS, INC.,

Defendants.

TAKEDA CHEMICAL INDUSTRIES, LTD. and
TAKEDA PHARMACEUTICALS NORTH AMERICA,
INC.,

Plaintiffs,

-v-

WATSON PHARMACEUTICALS, INC., WATSON
LABORATORIES, INC., WATSON PHARMA,
INC., and DANBURY PHARMACAL, INC.,

Defendants.

TAKEDA CHEMICAL INDUSTRIES, LTD. and
TAKEDA PHARMACEUTICALS NORTH AMERICA,
INC.,

Plaintiffs,

-v-

03 CIV. 8253 (DLC)

OPINION & ORDER

03 CIV. 8250

03 CIV. 8254

04 CIV. 1966

ALPHAPHARM PTY. LTD. and GENPHARM, :
INC., :
 :
Defendants. :
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Appearances:

For Plaintiffs:

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For Defendants Mylan Laboratories,
Inc., Mylan Pharmaceuticals, Inc., and
UDL Laboratories, Inc.:

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DENISE COTE, District Judge:

Mylan Laboratories, Inc., Mylan Pharmaceuticals, Inc., and UDL Laboratories, Inc. ("Mylan") have moved in advance of trial to preclude plaintiffs Takeda Chemicals Industries, Ltd. and Takeda Pharmaceuticals North America, Inc. ("Takeda") from presenting any documentary or testimonial evidence relating "in any way" to any purportedly missing Takeda laboratory notebooks. Mylan seeks to invalidate Takeda's '777 patent for the pioglitazone molecule on the ground that Takeda engaged in inequitable conduct in the prosecution of its patent application. For the following reasons, the motion is denied.

Several of Mylan's arguments in support of its inequitable conduct assertion are premised on a comparison of test data taken

from notebooks provided by Takeda to Mylan in discovery and the data regarding activity and toxicity presented by Takeda to the PTO. It is this comparison that underlies the instant motion. In its effort to carry its claim of inequitable conduct, the burden is on Mylan to show materiality and intent by clear and convincing evidence. Purdue Pharma L.P. v. Endo Pharmaceuticals Inc., 410 F.3d 690, 695 (Fed. Cir. 2005).

Essentially all of the data presented to the PTO by Takeda is taken from summary reports Takeda created contemporaneously with its research into compounds that might be useful for the treatment of diabetes.¹ These reports were used by the company and its research partner to make decisions about which compounds warranted further investigation. Mylan contends that it will be able to show at trial that the information provided to the PTO is false and misleading because it does not correspond to the testing data found in the Takeda notebooks. In making this argument, Mylan ignores entirely the contemporaneous reports created by Takeda to summarize and compare the results it obtained from testing many compounds, including the compound now known as pioglitazone.

Takeda explains that, for several reasons, it is inappropriate to rest any argument about the accuracy of its statements to the PTO on an examination of the notebooks produced in discovery. Among other reasons, it urges that any fair examination of the notebooks leads to the inevitable conclusion

¹The sole exception is for a limited quantity of data developed through testing done in response to a PTO Office Action. This portion of Mylan's inequitable conduct claim does not relate to that responsive testing.

that some of the notebooks from Takeda's testing program, which took place approximately two decades ago, are missing.

Mylan's motion should probably be characterized as an untimely discovery dispute. Fact discovery closed on May 27, 2005. At no point during the discovery period, however, did Mylan either take discovery concerning the missing notebooks, or raise with the Court Takeda's failure to comply with its discovery obligations in this regard. Moreover, Mylan does not assert now that Takeda either failed to conduct a diligent search for, or failed to produce, all extant notebooks with relevant data. Having missed its opportunity to obtain more information from Takeda during discovery about the missing notebooks, Mylan cannot be heard to complain at this late date that, in response to Mylan's arguments, Takeda may offer the explanation that certain testing data is now missing.

Mylan argues that Takeda should be prevented from using alternative evidence, that is, its contemporaneous reports, to prove the content of the missing notebooks. Takeda is not seeking to do so. Takeda is intending to rely on the reports to demonstrate its bona fides in its presentations to the PTO. To the extent Mylan wants to go behind the reports and build accusations from original testing data, then it is entirely appropriate for Takeda to respond by pointing out that Mylan's argument is, among other things, built on an incomplete set of data.

Conclusion

Having considered these and Mylan's other arguments in support of its motion, Mylan's motion in limine to preclude Takeda from presenting evidence relating to missing laboratory notebooks is denied.

SO ORDERED:

Dated: New York, New York
January 12, 2006



DENISE COTE

United States District Judge